

REMARKS

The present Amendment is in response to the Official Action mailed July 25, 2008. Because of the finality of the Action, the present Amendment is being submitted with a Request for Continued Examination. Claims 1, 3, 4, 7, 13, 15, and 17 have been amended, and claims 8-12 and 18-20 have either been canceled herein or previously canceled. Therefore, claims 1-7 and 13-17 remain pending in the present case. The following sets forth Applicants' remarks pertaining to the currently pending claims and the outstanding Action.

As an initial matter, Applicants thank the Examiner for conducting the telephone discussions of January 14 and 16, 2009 with the undersigned. In those discussions, the above-made amendments to the claims were discussed in light of the cited prior art, namely, in view of U.S. Patent No. 6,113,637 to Gill et al. ("Gill"). Moreover, Applicants pointed out that the present case includes similarly claimed subject matter to at least three other cases in the family cases related to the present matter. Specifically, the present case includes similarly claimed subject matter to that claimed in U.S. Patent Application Serial Nos. 10/781,505, 10/781,506, and 10/781,507, all of which are being handled by a different Examiner. In an Information Disclosure Statement accompanying the present case, those three cases, as well as prior art cited in connection with them, have been listed. As was conveyed in the aforementioned discussions, should the Examiner wish to review any prosecution documents pertaining to any of these cases, Applicants would be glad to provide copies of same.

Turning now to the substance of the Action, the Examiner set forth the following rejections of the previously presented claims:

- Claims 1, 2, 5-7, 15, 17, 19, and 20, under 35 U.S.C. § 103(a) as being obvious over the combination of

Gill and U.S. Patent No. 6,174,311 to Branch et al. ("Branch").

▪ Claims 3, 4, 7, 13, and 14, under 35 U.S.C. § 103(a) as being obvious over the combination of Gill, Branch, and U.S. Patent Application Publication No. 2002/0004683 to Michelson ("Michelson").

▪ Claim 16, under 35 U.S.C. § 103(a) as being obvious over Gill, Branch, and U.S. Patent No. 4,105,407 to Sanderson ("Sanderson").

In short, the Examiner removed previously presented anticipatory rejections that were set forth solely in view of Branch, in favor of obviousness rejections, each of which utilizes Gill as the primary reference. The Examiner asserted Gill as teaching each and every one of the limitations of, *inter alia*, independent claims 1, 15, and 17, save for a modular insertion plate, including a handle and a stem being connected by a bore and a tapered shaft. To support these limitations, the Examiner cited Branch as teaching an insertion tool that comprises modular pieces, including a handle fitting into the bore of a stem, and noted that it would have been obvious to one of ordinary skill in the art at the time of the present invention to modify the insertion tool of Gill to include modular pieces in view of the teachings of Branch. Moreover, the Examiner cited either Michelson or Sanderson as teaching the further limitations of claims 3, 4, 7, 13, 14, or 16, which the Examiner acknowledged are not taught by even the combination of Gill and Branch. As will be discussed more fully below, Applicants believe certain claim amendments made herein overcome the rejections set forth in the Action.

The insertion plate arrangement of the present invention is very different from that of the cited art. Namely, the elements referred to in Gill as constituting an insertion plate operate in a very different fashion than the insertion plate of the

present invention. First, the insertion plate of *Gill* is not removably connected with an insertion handle, as is acknowledged by the Examiner. Second, the insertion tool of *Gill* is only capable of being connected to holes in the flange of the intervertebral disc replacement device shown in that reference that are ultimately meant to receive bone screws for fixing the device to the adjacent vertebral bones. This is best shown in Fig. 15b of *Gill* where locking cam screws (90) are placed through apertures (80) and into apertures (36) and (56) of the intervertebral disc replacement device of that reference. Apertures (80) are designed so as to be slightly larger than the heads of screws (37), which are used to fixed components (22 and 24) of prosthesis (20) to their respective vertebrae. In other words, in order to ultimately fix the intervertebral disc replacement device to the adjacent vertebral bodies utilizing the components taught in *Gill*, screws must be placed through unoccupied apertures in the "insertion plate" of *Gill* in order to partially fix the prosthesis components to the vertebrae. Thereafter, the insertion tool must be removed (or at the very least uncoupled from the prosthesis) to allow the remaining two screws to be placed through the prosthesis to completely fix its components to the vertebrae.

On the other hand, the present invention teaches an insertion plate 700 being coupled with mounting screw holes 509, 609 of the intervertebral disc replacement device 400, thereby leaving bone screw holes 508a, 508b, 608a, 608b capable of receiving bone screws while the insertion plate is still coupled to the device. The design of insertion plate 700 is such that no portion of the plate extends over the bone screw holes. Moreover, insertion plate 700 is detachably coupled with an insertion handle 800, so as to allow for the construct made up of device 400 and insertion plate 700 to be manipulated by the handle when coupled and to stand alone when uncoupled. As is

more specifically set forth in paragraph [0069] of the originally filed specification of the present case, this provides the benefit of placing the two components of the intervertebral disc replacement device in a familiar fashion to a surgeon, *i.e.*, similar to that of a spinal plate (an example of which is shown in Figs. 13a-13d of the present case). This is indeed a significant and patentable difference between the present invention and that of *Gill*.

In the present amendment, Applicants have amended, among other claims, independent claims 1, 15, and 17 to more particularly capture these differences. Specifically, independent claim 1 has been amended to further describe the configuration of the insertion plate and how it engages with the first and second members of the two-piece intervertebral disc replacement device. That claim now requires, *inter alia*, that a first mounting element of the insertion plate engage a first mounting hole of a first member of the two-piece intervertebral disc replacement device and a second mounting element of the insertion plate engage a second mounting hole of a second member of the intervertebral disc replacement device, while a perimeter of the insertion plate does not extend over the bone screw holes of the first and second members. This, in essence, captures the configuration that allows for the spinal plate-like construction of the device, as well as for the first and second members to be maintained in registration with one another during insertion and coupling to the vertebrae. Moreover, independent claim 15 has been amended in a similar fashion, with the additional limitation that the first and second members are oriented "in a configuration substantially similar to that of a spinal fusion plate when viewed from an anterior vantage plate." Finally, independent method claim 17 has been amended to include two additional steps, namely, detaching the handle from the insertion plate and coupling the first and second members to the

vertebral bones while the insertion plate remains coupled with the first and second members.

Gill only contemplates connecting its "insertion plate" with holes in the flanges of the intervertebral disc replacement device that are ultimately meant to receive bone screws. Thus, the "insertion plate" of *Gill* must be removed prior to placing bone screws therethrough or else that element would ultimately be fixed along with the first and second members of its intervertebral disc replacement device to the adjacent vertebral bodies. With respect to independent claims 1 and 15, *Gill* does not teach the engagement of the first and second mounting elements of the insertion plate to the first and second mounting holes of the first and second members of the intervertebral disc replacement device either so as to not cover the bone screw holes or so that the first and second members are oriented in the configuration substantially similar to that of a spinal fusion plate when viewed from an anterior vantage point. In the aforementioned telephone discussions with the Examiner, she indicated that such amendments to independent claims 1 and 15 would overcome the rejections of such claims in view of *Gill* and *Branch*. Additionally, and with respect to independent claim 17, such method claim has been amended to include the steps of detaching the handle from the insertion plate and coupling the first and second member to the vertebral bones while the insertion plate remains coupled with the first and second members. As was acknowledged by the Examiner, neither *Gill* nor *Branch* teach these additional steps. Therefore, independent claim 17 also overcomes the rejection in view of the combination of those references.

In conclusion, none of the newly added limitations to the currently pending independent claims are taught by the prior art of record, most notably, *Gill* and *Branch*. Thus, even the various combinations used to reject the previously present

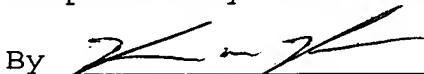
claims in the Action fail to teach each and every one of the limitations of independent claims 1, 15, and 17, as amended. Therefore, applicants respectfully submit that independent claims 1, 15, and 17, as amended, overcome the rejections set forth in the Action. Although not specifically discussed herein, each of the remaining dependent claims also overcome the rejections set forth in the Action based upon their proper dependence from one of independent claims 1, 15, or 17, or an intervening claim. Moreover, certain of these allowable dependent claims may, in fact, include subject matter even more clearly not taught by the prior art, and Applicants reserve the right to argue such at a later date, if necessary. Therefore, in light of all of the above, Applicants respectfully request allowance of each and every one of the currently pending claims.

As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited. If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that she telephone Applicants' attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Dated: January 21, 2009

Respectfully submitted,

By 
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